RESEARCH ARTICLE

Development and Validation of Stability Indicating RP-HPLC Method for Simultaneous Assessment of Dapagliflozin and Metformin in their Pure Forms and in Presence of Selected Excipients

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ABSTRACT
Excipients are crucial in formulating dosage forms. However, under stressful environmental conditions, they might interact with the active pharmaceutical ingredient, potentially diminishing the drug's efficacy. The present research article investigates the crucial role of excipients, with a key focus on compatibility evaluations of Dapagliflozin and Metformin with selected excipients mixture, including Polyvinaylpyrolidon K90F, microcrystalline cellulose, Croscarmellose sodium and Magnesium stearate. The analysis used an Inertsil ODS-3V column. The mobile phase, consisting of Water: Methanol in the ratio of 25:75v/v. The pH of the mobile phase was adjusted to 3 using orthophosphoric acid. The detection was done at 225nm. The range value for Dapagliflozin and Metformin were observed as 20-80µg/mL and 0.4-1.6µg/mL, respectively with the respective retention time of 2.1 for Metformin and 8.9 for Dapagliflozin. A forced degradation study was performed on Dapagliflozin and Metformin, in their pure forms and in combination with selected excipients and formulations. The comparison of effects of stress conditions were observed and concluded in the presence of selected excipients and in the commercially available formulation containing Dapagliflozin and Metformin. The extensive evaluation of Dapagliflozin and Metformin compatibility with selected excipients under various conditions offered valuable insights into their stability and practical utility.

Keywords: Dapagliflozin, Metformin, Forced degradation, RP-HPLC, Diabetic mellitus
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INTRODUCTION

Managing diabetes mellitus requires a comprehensive strategy that addresses its complexities through continuous interventions aimed at controlling blood sugar levels and mitigating cardiovascular risk factors, thereby reducing the likelihood of both acute and chronic complications.[1] Numerous medications are available to manage diabetes, and the combination of Dapagliflozin (DG) and Metformin (MT) stands out as one of the most frequently prescribed. This combination is highly preferred for diabetes treatment due to its unique advantages. MT assists in regulating glucose levels and may facilitate weight loss, while DG provides sustained weight reduction and offers additional benefits such as reducing the risks associated with kidney and cardiovascular issues.[2] The synergistic action of DG and MT contributes to reducing blood glucose levels in individuals diagnosed with type 2 diabetes.[3] Excipients are essential for ensuring drug stability and uniformity. In this study, various excipients, including Polyvinylpyrrolidone K90F, Microcrystalline Cellulose, Magnesium Stearate, and Croscarmellose Sodium, were evaluated for their effects on the degradation of the selected active pharmaceutical ingredients. These excipients were selected based on published patents for DG and MT combined formulations.[4,5]

The analytical methods reported for the analysis of DG and MT encompass UV spectroscopy,[6] HPLC,[7] and HPTLC.[8] Additionally, stability-indicating method using RP-HPLC[9] is available for the measurement of MT and DG. To ensure the stability and uniformity of dosage forms, it is necessary to incorporate excipients, which are pharmacologically inert. However, some of these excipients, might interact with the active pharmaceutical ingredient, leading to chemical degradation.[10,11] This interaction could potentially produce harmful degradation products and diminish the drug's efficacy.[12,13] The dosage form chosen for this study combines DG and MT in solid oral dosage form, a formulation that has recently received approval from the USFDA. The chemical stability of MT and DG in the presence of excipients is crucial for maintaining product quality throughout its shelf life. A significant gap exists in the development of a stability-indicating RP-HPLC Method

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for the simultaneous assessment of DG and MT in their pure forms and with selected excipients. Spectroscopy and chromatography are highly effective tools for conducting preliminary investigations into stability and performing quantitative analysis of multicomponent mixtures.[14-17] The current research is aimed to assess the stability and degradation of MT and DG under different stress conditions, both in the presence of specific excipients and within the product formulation, using RP-HPLC.

MATERIALS AND METHODS

Material

Pure samples of MT and DG were obtained from Sidmak Laboratories Pvt. Ltd, Valsad, Gujarat, India, and Hetero Drugs Ltd., Hyderabad, India, respectively. Various excipients used throughout the research, including Polyvinylpyrrolidone K90F, were obtained from Sun Pharmaceuticals Industries Ltd, Vapi, Gujarat, India. Microcrystalline Cellulose, Magnesium Stearate, and Croscarmellose Sodium were sourced from Chemdyes Corporation, Vadodara, Gujarat, India. Orthophosphoric acid and hydrogen peroxide were obtained from Om Labchem Laboratory, Vapi, Gujarat, India. Additionally, the respective reagents for the research were obtained from licensed vendors with HPLC-grade or analytical-grade quality.

Instruments

The analysis was performed using a Waters 2695 HPLC Separation Module (Waters, Milford), which featured a UV detector and an autosampler injector. Chromatographic separation was achieved using an Inertsil ODS-3V column (4.6 × 250 mm, 5 µm). Data monitoring and integration were performed using Empower 3 software. Instruments

Table 1: Optimised stress conditions for force degradation studies

Stress conditions	Respective reagent/ Required equipments	Exposure	Duration
Acidic	0.1N HCl	Room Temperature	15 minutes
Basic	0.1N NaOH	Room Temperature	10 minutes
Oxidation	3% H_2O_2	Room Temperature	10 minutes
Photolysis	1mm Petri-dish	Ultra-violet light	960 minutes
Thermal	Oven	70ºC	120 minutes

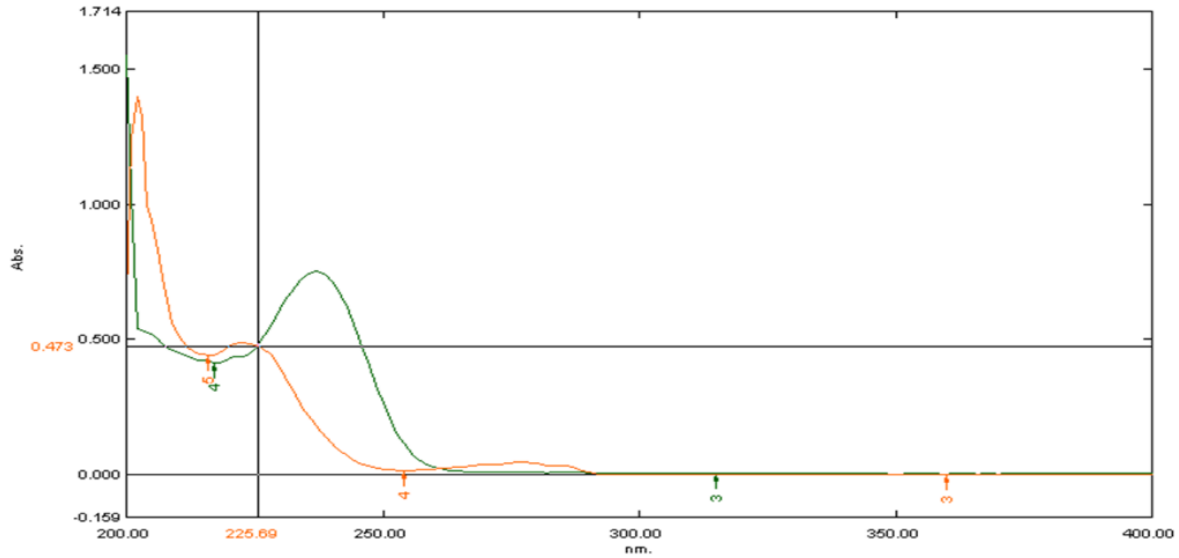

Figure 1: The Overlay Spectra of DG and MT by UV-Spectroscopy

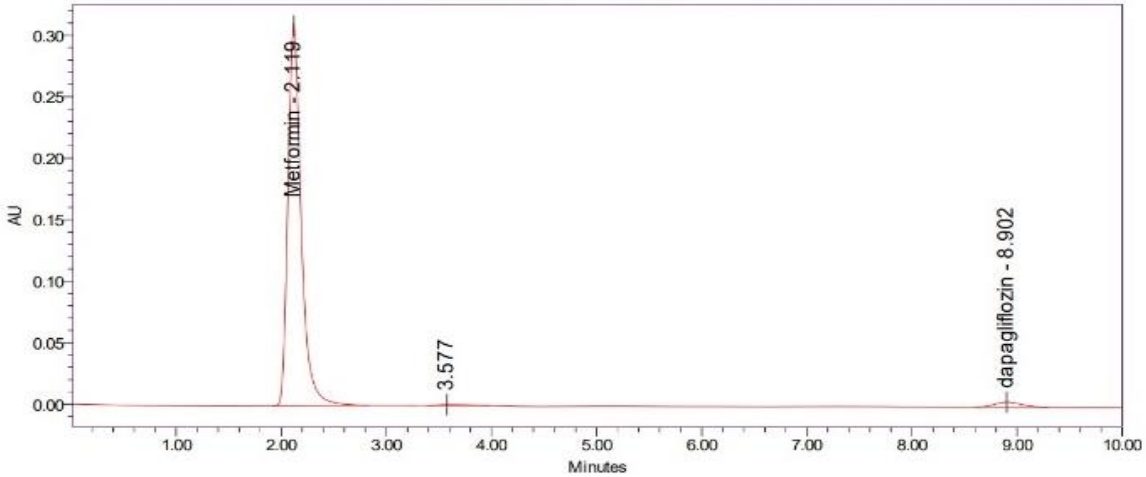

Figure 2: The chromatogram of mixture of pure DG and MT

used in the research included an FTIR instrument (Bruker, Germany), a digital weighing balance (MTtler Toledo, Switzerland), UV-Visible SpectrophotoMTers (Shimadzu, Japan, models 1700, 1800, 1900i), a melting point apparatus (Veego, India), and a pH MTer (Elico LIT 20, Elico, India). Experimental procedures also involved the use of a vacuum filter assembly (Crompton Greaves Ltd., Maharashtra, India), a hot air oven (Bombay Labchem, Maharashtra, India), an ultrasonicator (Raj Analytical Solution Pvt. Ltd., Punjab, India), and a UV chamber (Durga Scientific Pvt. Ltd., Gujarat, India).

Methods

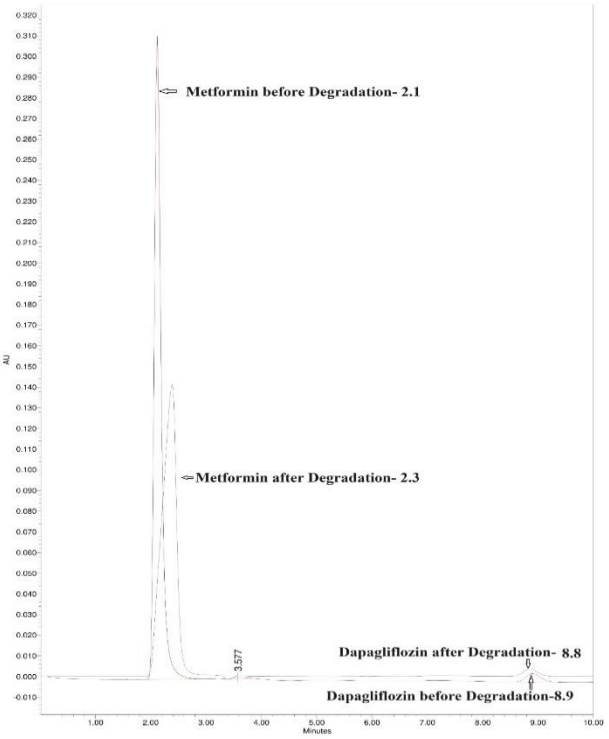

Figure 3: Overlay chromatogram of DG and MT – standard mixture before and after applying acidic stress conditions.

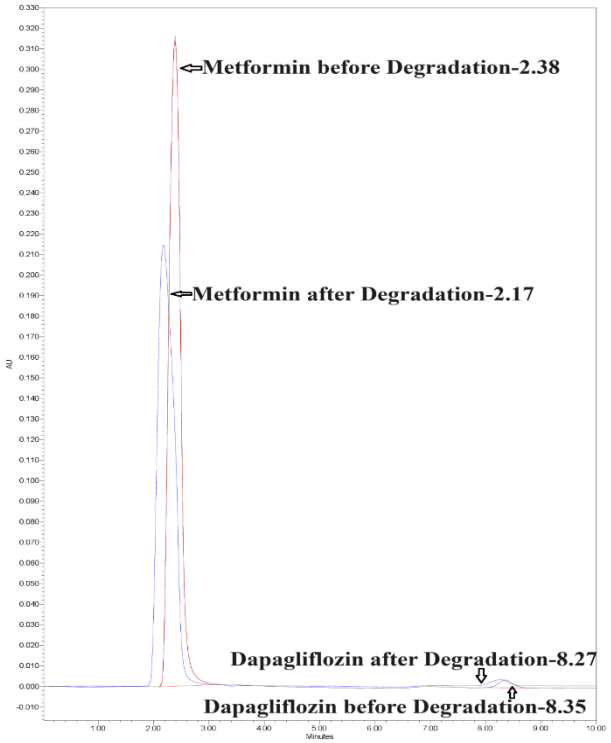

Figure 4: Overlay chromatogram of DG and MT – standard mixture before and after applying basic stress conditions.

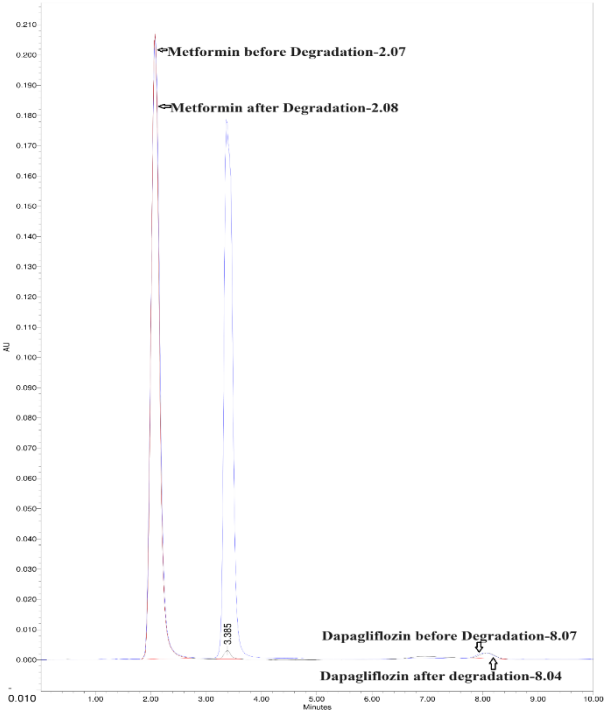

Figure 5: Overlay chromatogram of DG and MT – standard mixture before and after applying oxidative stress conditions.

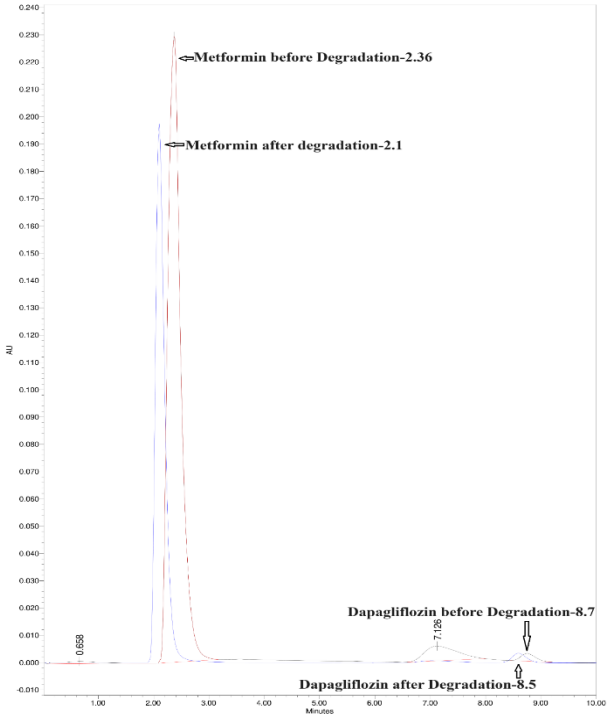

Figure 6: Overlay chromatogram of DG and MT – standard mixture before and after applying thermal stress conditions.

Table 2. Results of force degradation studies of DG and MT in the presence of selected excipients and in commercial formulation

Type of stress conditions	Duration (Minutes)	% degradation					
		DG + MT (Standard)		DG + MT (In the presence of selected excipients)		DG + MT (Commercial formulation)	
		DG	MT	DG	MT	DG	MT
Acid	15	13.4	14.3	10	10.1	11.2	10.5
Base	10	18.9	12	10.2	6.5	17.7	6.1
Oxidation	10	17.5	15.9	5.9	8.5	6.5	3.8
Photolysis	960	17.7	17.3	16.7	11.3	9.2	10.5
Thermal	120	15.5	18.1	12.6	13.9	3.3	3.9

Table 3. The result of System Suitability for DG and MT

Conc. (µg/ml)		Retention Time		Theoretical Plates		Tailing Factor		Resolution
MT	DG	MT	DG	MT	DG	MT	DG	
50	1	2.087	8.902	2483	5975	1.2	1.1	19
50	1	2.087	8.895	2483	6144	1.2	1.1	19.9
50	1	2.085	8.984	2475	6107	1.2	1.1	19.9
50	1	2.079	8.97	2510	6043	1.2	1.2	19.9
50	1	2.094	8.871	2355	6222	1.3	1.1	19.6
50	1	2.098	8.91	2446	5988	1.2	1.2	19
Mean		2.088	8.917					
%RSD		0.322	0.480					
Acceptance criteria		<2%		>2000		<1.5		>2

Table 4. The results of accuracy study

Drug	%Level	Amount of Sample Mixture (µg/ml)	Amount of standard spiked (µg/ml)	Total sample (µg/ml)	Recovered std amount (µg/ml)	*% Recovery	Mean Recovery
MT	50	25	12.5	37.5	12.62	101	101 ± 0.68
	100	25	25	50	25.17	100.7	
	150	25	37.5	62.5	38.25	102	
DG	50	0.5	0.25	0.75	0.247	98.9	99.63± 1.18
	100	0.5	0.5	1.0	0.505	101	
	150	0.5	0.75	1.25	0.742	99	

*n = 3

Scanning wavelength and Chromatographic conditions

The standard solution was scanned using a UV spectrophotometer across a range of 200nm to 400nm in spectrum mode, with Methanol serving as the reference solvent. The chromatographic measurement was performed at 225 nm as an optimized scanning wavelength. The mobile phase consisted of Methanol and water in a 75:25 v/v ratio, adjusted to pH 3 with OPA. The flow rate was set at 0.8 ml/min, and detection was performed at 225 nm. The total runtime for the analysis was 10 minutes. A wavelength of 225 nm was selected for the chromatographic conditions in further research on DG and MT.

Preparation of standard solutions

A degassed mixture of Methanol and water in a 75:25 %v/v ratio was prepared and used as a diluent for further Method development and validation. Accurately weighed amounts of 5 mg of DG and 25 mg of MT were transferred into separate 10 ml voluMTric flasks. Each flask was then filled to the mark with the appropriate diluent, resulting in solutions with concentrations of 500µg/ml for DG and 2500µg/ml for MT. From these standard stock solutions, further aliquots were prepared to achieve concentrations of 5 µg/ml for MT and 1 µg/ml for DG. Similarly, a mixture of MT and DG along with selected excipients was prepared by accurately weighing 5 mg of DG and 250 mg of MT, which were introduced into a 10 ml voluMTric flask. Additionally, 5 mg each of Polyvinylpyrrolidone K90F, microcrystalline cellulose, Croscarmellose sodium, and Magnesium stearate were added into the flask. Subsequently, further aliquots were prepared, resulting in final concentrations of 1 µg/ml for DG, 50 µg/ml for MT, and 1 µg/ml for the respective excipients. The solution for commercial formulation analysis containing DG and MT was prepared by taking an equivalent amount of the mixture of MT and DG according to a ratio of 50:1 µg/ml, which was withdrawn from the synthetic mixture and dissolved in a specific solvent, and the volume was subsequently adjusted to 10 ml. Further aliquots were prepared, resulting in final concentrations of 1 µg/ml for DG and 50 µg/ml for MT.

Stability of working solution

Table 5: Results of Robustness study of MT and DG

Parameter 1 – Minor modification in detection wavelength					
Drug	Conc. (µg/ml)	Detection wavelength	Retention time	AUC	*%RSD
MT	50	224	2.1	2942300	1.104
		225	2.09	2974338	
		226	2.08	2909680	
DG	1	224	8.9	373343	1.47
		225	8.8	372122	
		226	8.9	372936	
Parameter 2 – Minor modification in Flow Rate					
Drug	Conc. (µg/ml)	Flow rate (ml/min)	Retention time	AUC	*%RSD
MT	50	0.7	2.1	2974338	0.127
		0.8	2.1	2977833	
		0.9	2.0	2981911	
DG	1	0.7	8.8	375784	0.909
		0.8	8.9	374970	
		0.9	8.9	375377	
Parameter 3 – Minor modification in mobile phase ratio					
Drug	Conc. (µg/ml)	Mobile phase ratio Methanol:Water	Retention time	AUC	*%RSD
MT	50	74:26	2.11	2911427	1.11
		75:25	2.09	2920165	
		76:24	2.08	2971426	
DG	1	74:26	8.7	375377	0.917
		75:25	8.8	374563	
		76:24	8.9	374970	

* n=3

The stability of both working solutions containing DG and MT was established under both room temperature and freezing conditions using optimised chromatographic conditions.

Forced Degradation Study

For force degradation studies, as mentioned in the introductory part, hydrolytic conditions, thermal conditions, oxidative conditions, and photolytic conditions were applied according to the standard guidelines of pharmaceutical stability studies by ICH. For each condition, the specific degradation parameters were optimized, as represented in Table 1. After optimizing the standard conditions, specific solutions of pure mixtures of DG and MT, the pure mixture of DG and MT along with the selected excipients, and a sample of commercial formulation containing DG and MT were prepared within the linearity range for further stability studies and conclusions for each respective combination.

Method Validation

The guidelines outlined in the International Council for Harmonisation were followed for Method validation. Various parameters were tested as per the guidelines for the validation of the developed analytical Method. System suitability was tested by injecting six replicates of freshly prepared standard solutions of DG and MT, and the results were recorded. The essential parameters such as the tailing factor, number of theoretical plates, retention time, and resolution were documented to obtain system suitability. The specificity of the method was tested by comparing the standard mixture of DG and MT with the blank and samples of commercial formulations containing both DG and MT, without any prior separation or purification steps. The accuracy of the Method was tested by conducting recovery of the standards in the pre-analysed formulation containing DG and MT at three different levels of standards, i.e., 80%, 100%, and 120%. The percentage of standard recovered was calculated. Precision was assessed by determining Method variations intra-day and inter-day. Repeatability involved injecting the standard solution six times at concentrations of 50:1 µg/ml on the same day. Results were expressed as relative standard deviation or the coefficient of variance. The robustness of the Method was determined by applying minor changes in Method parameters in the form of the ratio of mobile phase, scanning wavelength, and flow rate. LOD and LOQ were determined as per the equation given in ICH guidelines.

RESULTS AND DISCUSSION

Optimization of Scanning wavelength and chromatographic conditions

The standard solution was scanned in a UV spectrophotometer between 200nm to 400nm in spectrum mode and the overlay spectra of DG and MT pure drugs was shown in Figure 1 as represented below. As per the overlay spectra of DG and MT, 225nm was selected as a common wavelength for further Method development and validation. Optimal system suitability was achieved after testing various mobile phases, with the best results obtained using a methanol-to-water ratio of 75:25% v/v, adjusted to pH 3 with orthophosphoric acid. An Inertsil ODS-3V column

Table 6. Results of Validation Parameters

Parameters	DG	MT
Range (µg/ml)	0.4-1.6 µg/mL	20-80µg/ml
Regression Equation	y = 58251x + 15770	y = 40693x + 330615
Correlation Coefficient	0.9979	0.9984
Accuracy (%±SD)	99.6 ±1.18	101.2 ± 0.68
Repeatability (%RSD)	1.5	1.12
Intra-day Precision (%RSD)	0.75	0.88
Inter-day Precision (%RSD)	1.06	1.0
LOD (µg/ml)	0.07	0.23
LOQ (µg/ml)	0.23	0.72
Robustness (%RSD)		
With Different wavelength	1.104 0.127	1.47 0.909
With Different flow rate	1.11	0.917
With Different mobile phase ratio		

(4.6 × 250 mm, 5 µm) was employed as the stationary phase for chromatographic separation throughout the research. Before injection, the mobile phase was filtered through a 0.45 µm membrane filter and degassed to eliminate dissolved gases. The mobile phase was flowed at a constant rate of 0.8 ml/min. Each sample was analysed for a total run time of 10 minutes under these optimized conditions, with detection carried out at a wavelength of 225 nm. The chromatogram corresponding to DG and MT in their pure mixture is presented in Figure 2.

Stability of working standard solution

The stability of both working solutions containing DG, MT, and selected excipients was tested under both room temperature and freezing conditions under optimized chromatographic conditions. As a result, no significant degradation or alteration in stability was detected in either the DG and MT solutions under the specified conditions. Stability was maintained by all the solutions at room temperature in their respective solvents for 30 hours and for 48 hours under freezing conditions.

Forced degradation study

As outlined in the procedure, a forced degradation study of the mixture of DG and MT in their pure form, in the presence of selected excipients, and in commercial formulations was conducted under hydrolytic, thermal, oxidative, and photolytic conditions. A brief comparison of the behaviour of DG and MT in the presence of selected excipients and in the formulation was obtained after applying various stressful conditions. Significant degradation was observed for both DG and MT after applying various stress conditions. However, the percentage of degradation for both compounds significantly decreased in the presence of selected excipients and in the commercial formulation containing DG and MT. The chromatograms for the forced degradation studies of the standard mixture of DG and MT under various stressed conditions are presented in Figures 3 to 7. As shown in the Figure 7, a strong additional peak of degradation product was obtained at the retention time of 3.389. As shown in Figure 9, after applying photolytic optimised stress conditions, additional degradation peak was observed at RT – 7.126. Similarly, different chromatogram were obtained for the forced degradation studies of DG and MT in the presence of selected excipients and in the commercial formulation. The comparative results of the forced degradation studies, along with overall observations, are presented in Table 2.

Analytical Method Validation

The % RSD for retention time was found to be 0.322 for MT and 0.1939 for DG, meeting the acceptance criteria of < 2. The theoretical plates for six replicates of both MT and DG were greater than 2000, and the tailing factor was below 1.5. Additionally, the resolution was greater than 2. These results, falling within the acceptance criteria, indicate the Method and system's adequacy for analysis. The developed Method was validated following ICH guidelines, with the system suitability test results detailed in Table 3. As outlined in the procedure, the Method's accuracy was assessed by adding standard samples of MT and DG to pre-analyzed formulation samples at three different levels: 50%, 100%, and 150%. The percentage of MT and DG standards was calculated, and the results are presented in Table 4 below.

The detailed results of Robustness testing were represented in Table 5, and the results of validation parameters were represented in Table 6, respectively, as mentioned in table. All validation parameters were found to be within the acceptance criteria as per the ICH Q2(R2) guideline. The proposed Method was deemed simple, rapid, accurate, precise, and specific, with the capability to determine DG and MT in the dosage form.

CONCLUSION

The degradation study of DG and MT was conducted in their pure forms and in the presence of selected excipients and their combined formulation. DG predominantly degraded under alkaline conditions, while MT showed significant degradation under thermal conditions. Comprehensive degradation studies concluded that selected excipients significantly reduce the degradation of both DG and MT compared to their degradation in pure form. In the commercial formulation containing both drugs, significantly lower degradation was observed under the same stress conditions. Thus, excipients play a crucial role in reducing the degradation likelihood of both drugs. This degradation study was valuable in identifying whether new degradation pathways or products emerged when the active pharmaceutical ingredients were subjected to exaggerated storage conditions alone or with excipients. Additionally, the study has implications for targeted delivery systems.

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